



The Vitamin Marketing Experts

March 9, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

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Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING ZINC 15 mg. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING ZINC 15 mg were first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

"Essential part of over 100 enzymes that aid in reproduction, digestion, metabolism and wound healing."

"The added zinc in this formula is important to reproductive organs and normal functioning of the prostate gland"

Very truly yours,

MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs

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STUDIES FOR ZINC CLAIMS

Skandhan, K.P. et al; "Serum electrolytes in normal and infertile subjects. II. Zinc" *Experientia*, 34 (11); 1476-1477, 1978

Netter, A., et al; "Effect of zinc administration on plasma testosterone, dehydrotestosterone and sperm count." *Arch Androl*, 7: 69, 1981

Solomons, N.W. "On the assessment of zinc and copper nutriture in man" *Amer Journ Clin Nut.* 32: 856-871, April 1979